



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC 28 2004

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Sally Hayes, Agent
Scientific & Regulatory Consultants, Inc.
P.O. Box 1014
Columbia City, IN. 46725

Subject: Oculus Innovative Sciences, Inc.
Oculus Microcyn Disinfectant
EPA Registration Number 81206-1
Telecom Amendment Date: October 20, 2004
Revised label Date: Dec. 27, 2004

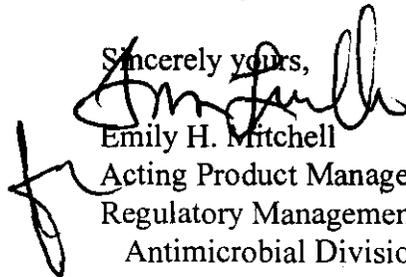
Dear Ms. Hayes:

The amendment referred to above, submitted in connection with registration of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable with the following conditions:

- A 12 month storage stability study is required and must be submitted by March 31, 2006. See enclosed Product Chemistry Review for additional information.
- 3 copies of your revised Eye and Dermal acute toxicity studies must be submitted in accordance with PR Notice 86-5 and any deficiencies cited in the forthcoming reviews must be rectified. Based on our preliminary review, we will allow the removal of the signal word based on Category IV findings.
- On pages 2 and 7 delete the word **Decontaminant**.
- On page 6 fix typo under the second number 7 direction.

A copy of your conditionally stamped acceptable label is enclosed. Make the necessary corrections and submit two copies of your revised labeling to our office for our files. If you have any questions regarding this letter, please contact Tom Luminello of my staff at (703) 308-8075.

Sincerely yours,


Emily H. Mitchell

Acting Product Manager (32)
Regulatory Management Branch II
Antimicrobial Division (7510-C)

Enclosures

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Oculus Microcyn Disinfectant (OMD)

with Microcyn™ Technology

Bactericidal
Tuberculocidal in 5 minutes
Virucidal†

Hospital-Grade Disinfectant
pH Balanced Oxidized Water with Chlorine and ionic stabilizers such as
H₂O₂, ClO₂ and O₃

READY TO USE
(No Mixing, Activating or Dilution Required)

Formulated for Effective Disinfection in Households
Formulated for Effective Disinfection in Hospitals
Formulated for Effective Disinfection in Industrial Areas

Hospital Disinfectant Cleaner
Instrument Presoak
Disinfectant Cleaner

ACCEPTED
With COMMENTS
in EPA Letter Dated!

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

ACTIVE INGREDIENTS:

Sodium Hypochlorite* 0.00357%
Hypochlorous Acid* 0.00252%
OTHER INGREDIENTS... 99.99391%
TOTAL.....100.00000%

*68 ppm available chlorine

Net Contents {Insert Contents Here}
EPA Reg. No. 81206-1
EPA Est. No. {Insert EPA Est. No. Here}

81206-1

Keep Out of Reach of Children

Manufactured by:
Oculus Innovative Sciences, Inc., 1129 N. McDowell Blvd., Petaluma, CA 94954

Note: Bracketed [] information is optional text. Text separated by a comma (,) denotes—and/or—options.
{Bracketed Text} is for administrative purposes only and will not appear on the printed label.

{additional optional product claims that may be on front panel or any other panel}

Institutional Disinfectant Cleaner
 Dental Disinfectant Cleaner
 Veterinary Disinfectant Cleaner
 Medical Disinfectant Cleaner
 Surface Disinfectant Cleaner
 Laboratory Disinfectant Cleaner
 Household Disinfectant Cleaner
 Commercial Facility Disinfectant Cleaner

Formulated for Effective Food Contact Sanitization
 Food Contact Sanitizer

[DESCRIPTION]

Oculus Microcyn Disinfectant (OMD) is a hospital-grade multi-purpose disinfectant/decontaminant cleaner and food contact sanitizer for use on hard non-porous inanimate surfaces. Oculus Microcyn Disinfectant (OMD) is a super-oxidized, pH-neutral, purified water-based solution. It is a broad-spectrum, ready-to-use product that is especially useful in patient care areas, households, child care facilities, health clubs, laboratories and on food contact surfaces where cross-contamination of treated surfaces can occur. Oculus Microcyn Disinfectant (OMD) will effectively disinfect hard, non-porous surfaces such as non-critical medical devices, countertops, sinks, showers, surgical tables, doorknobs and floors when used in accordance with the Directions for Use.

[FEATURES]

Fast-Acting
 Broad-Spectrum Disinfectant [and Sanitizer]
 No special handling or disposal requirements
 Durable, stable solution with 1 year shelf life
 Non-corrosive
 Non-flammable
 Multi-functional
 No dilution or mixing required
 Effective under ambient temperatures
 No expensive machinery or equipment required
 Kills virus and bacteria on hard non-porous [inanimate] surfaces and food contact areas
 Ready-to-use: No dilution or mixing required
 Eliminates odors: Kills odor causing bacteria while simultaneously chemically neutralizing their odor

ACCEPTED
 WITH COMMENTS
 IN EPA LETTER DATED
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FOR USE ON HARD, NON-POROUS SURFACES IN:

<p>Homes:</p> <ul style="list-style-type: none"> ▪ Bathrooms ▪ Kitchens ▪ Laundry Rooms ▪ Bedrooms ▪ Family Rooms ▪ Porches ▪ Patios ▪ Garages ▪ Closets ▪ Pet Animal Quarters <p>Medical:</p> <ul style="list-style-type: none"> ▪ Hospitals ▪ Surgical Rooms ▪ Nursing Homes ▪ Dental Offices ▪ Emergency Rooms ▪ Clinics ▪ Isolation Areas and Quarantine Rooms ▪ Neonatal Units ▪ Ophthalmic and Optometric Facilities ▪ Eye Surgical Centers ▪ Critical and Intensive Care Units <p>Government:</p> <ul style="list-style-type: none"> ▪ Military Quarters ▪ Barracks ▪ Postal Offices ▪ Customs/Immigration Facilities ▪ Political Offices and Environments 	<p>Commercial:</p> <ul style="list-style-type: none"> ▪ Office Buildings, ▪ Recreational Facilities ▪ Restaurants And Bars ▪ Convenience Stores ▪ Food Processing Plants ▪ Food Storage Areas ▪ Institutional Kitchens ▪ Athletic/Exercise Facilities ▪ Barber Shops ▪ Prisons ▪ Correctional Facilities ▪ Dressing Rooms ▪ Factories ▪ Public Rest Rooms ▪ Hair and Nail Salons ▪ Tanning Salons ▪ Camp Grounds ▪ Kennels ▪ Pet Shops ▪ Zoos ▪ Fire Stations ▪ Police Stations ▪ Laboratories ▪ Medical Device Manufacturing Facilities ▪ Mortuaries ▪ Morgues ▪ Animal Shelters and Kennels ▪ Beer/wine/liquor Production Facilities
<p>Accommodations:</p> <ul style="list-style-type: none"> ▪ Hotels ▪ Motels ▪ Mobile Homes ▪ Condos ▪ Bed & Breakfasts 	<p>Agricultural:</p> <ul style="list-style-type: none"> ▪ Dairy Farms ▪ Hog Farms ▪ Poultry Farms ▪ Turkey Farms
<p>Educational:</p> <ul style="list-style-type: none"> ▪ Pre-Schools ▪ Elementary Schools ▪ Grade Schools ▪ High Schools ▪ Colleges ▪ Universities ▪ Playgrounds ▪ Day Care Centers ▪ Cafeterias ▪ Gymnasiums ▪ Locker Rooms ▪ Shower & Bath Area 	<p>Transportation:</p> <ul style="list-style-type: none"> ▪ Cars ▪ Trucks ▪ Motorcycles ▪ Airplanes ▪ Trains ▪ Boats ▪ Buses ▪ Campers ▪ Emergency Vehicles ▪ Ships ▪ Taxis ▪ Trailers <p style="text-align: right;">DEC 28 2004</p> <p style="text-align: right;">81206-1</p>

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DISINFECTS THE FOLLOWING HARD NON-POROUS SURFACES

Appliances	Diaper Changing Tables	Mirrors	Stainless Steel
Anesthesia Machines	Doorknobs	Nail Files	Steamrooms
Animal Cages	Drinking Fountains	Non-critical Medical	Stoves
Automobile Interiors	Faucets	Equipment and	Stovetops
Bathroom Fixtures	Floors	Devices	Stretchers
Bathtubs	Garbage Cans	Oxygen Hood Surface	Surgical Beds/Tables
Bed Railings	Gardening Tools	Physical Therapy	Tables
Bidets	Gymnasium/Fitness	Equipment	Telephones
Cabinets	Equipment	Plexiglas®	Glazed Tile
Cages	Hair Cutter Blades	Razors	Toilet Exteriors
Chairs (sealed wood and metal)	Hair Dryers	Refrigerator Exteriors	Tubs
Computers	Hair/Nail Implements	Respiratory Equipment	Tweezers
Counters	Hand Rails	Salon Surfaces	Urinal Exteriors
Cribs	Highchairs	Saunas	Walls
Dental Irrigation	Litterboxes	Scissors	Workstations
Equipment Surfaces	Metal	Shampoo Bowls	
Eyeglasses	Manicure Tables	Showers	
Desks	Microwave Oven	Shower Doors	
	Exteriors	Sinks	

SANITIZES THE FOLLOWING HARD NON-POROUS SURFACES

Glass Baby Bottles	Food Contact Surfaces
Kitchen Utensils	Microwave Oven Exteriors
Food/Beverage Storage Container	Refrigerator Exteriors
Feed Containers	

MICROBIOCIDAL ACTIVITY

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Oculus Microcyn Disinfectant (OMD) kills the following bacteria and viruses:

Bactericidal	Salmonella choleraesuis - 10 minutes
	Staphylococcus aureus - 10 minutes
	Pseudomonas aeruginosa - 10 minutes
	Escherichia coli O157:H7 - 1 minute
Tuberculocidal	Mycobacterium tuberculosis var bovis - 5 minutes
Sanitizer	Salmonella typhi - 1 minute
Virucidal	HIV-1† - 10 minutes

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BACTERICIDAL: Passes AOAC Use-Dilution Test in 10 minutes against *Salmonella choleraesuis*, *Staphylococcus aureus* and *Pseudomonas aeruginosa* and against *Escherichia coli* O157:H7 in 1 minute in the presence of 5% organic soil (serum).

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TUBERCULOCIDAL: Passes AOAC Quantitative Tuberculocidal Test against *Mycobacterium tuberculosis*, var. *bovis* in 5 minutes in the presence of 5% organic soil (serum).

VIRUCIDAL: Passes ASTM Virucidal Test against HIV-1 in 10 minutes in the presence of 5% organic soil (serum).

SANITIZER: Equivalent to 100ppm available chlorine in an AOAC Available Chlorine Test in 1 minute against *Salmonella typhi*.

ODOR CONTROL

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Oculus Microcyn Disinfectant (OMD) eliminates many odors by killing odor-causing bacteria while simultaneously chemically neutralizing their odors.

DIRECTIONS FOR USE

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It is a violation of Federal Law to use this product in a manner inconsistent with its label.

To Disinfect:

For heavily soiled areas, a precleaning is required. Apply Oculus Microcyn Disinfectant (OMD) to hard non-porous surfaces with a cloth, mop, sponge, or coarse sprayer. Wet all surfaces thoroughly. Allow surface to remain wet for 10 minutes. Wipe surface using a paper or cloth towel or allow to air dry prior to use. Discard towel. The solution must be discarded after each use. For tuberculocidal activity Oculus Microcyn Disinfectant (OMD) is effective in 5 minutes at 20°C in the presence of 5% organic soil.

To Sanitize:

For heavily soiled areas, a precleaning is required. Apply Oculus Microcyn Disinfectant (OMD) to hard non-porous surfaces with a cloth, mop, sponge, or coarse sprayer. Wet all surfaces thoroughly. Allow surface to remain wet for 1 minute then air dry.

For dishes, glassware and utensils: Wash and rinse. After washing soak for at least one minute in Oculus Microcyn Disinfectant (OMD), drain and air dry.

†KILLS HIV-1 (AIDS VIRUS) ON PRECLEANED, ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces / objects with blood / body fluids, and in which the surfaces / objects likely to be soiled with blood / body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type I (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OF SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS:

Personal Protection: Disposable protective gloves, gowns, face masks, or eye coverings as appropriate must be worn during all cleaning of blood / body fluids and during decontamination procedures.

Cleaning Procedures: Blood / body fluids must be thoroughly cleaned from surfaces / objects before application of disinfectant.

Contact Time: HIV-1 (AIDS virus) is inactivated in 10 minutes at 20°C (77°F) (room temperature).

Disposal of Infectious Materials: Blood / body fluids should be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.

VETERINARY PRACTICE / ANIMAL CARE / ANIMAL LABORATORY / ZOOS / PET SHOP/ KENNELS DISINFECTION DIRECTIONS:

For cleaning and disinfecting the following hard nonporous surfaces: equipment not to be used for animal food or water, utensils, instruments, cages, kennels, stables, catteries, etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with potable water. Saturate surfaces with Oculus Microcyn Disinfectant (OMD) for a period of 10 minutes. Immerse handling and restraining equipment such as leashes, muzzles, halters or ropes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

For Farms, and Poultry Houses:

1. Remove all animals and feeds from premises, vehicles, coops, crates, and enclosures.
2. Remove all litter, manure and droppings from floors, walls and surfaces of barns, pens, chutes and other facilities occupied or traversed by animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate surfaces with Oculus Microcyn Disinfectant (OMD) for a period of 10 minutes.
6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, coops, vehicles, and other closed spaces. Do not house livestock, poultry or employ equipment until treatment has been absorbed, set, or dried.
7. Thoroughly scrub treated feed racks, troughs, mangers, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

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FOR PRECLEANING AND DISINFECTING MEDICAL SURFACES:**FOR PRECLEANING INSTRUMENTS, EQUIPMENT AND SURFACES PRIOR TO DISINFECTION:**

Apply Oculus Microcyn Disinfectant (OMD) directly to surface. Allow to remain wet for 30 seconds.

Wipe surface using a paper or cloth towel to dry. Discard towel.

FOR DISINFECTING NON-CRITICAL INSTRUMENTS AND EQUIPMENT SURFACES:

Thoroughly preclean surfaces prior to disinfection with Oculus Microcyn Disinfectant (OMD). Apply Oculus Microcyn Disinfectant (OMD) directly to precleaned surface, thoroughly wetting area to be disinfected. Allow surface to remain wet for 10 minutes at room temperature (69°F/20°C).

For tuberculocidal activity, Oculus Microcyn Disinfectant (OMD) is effective in 5 minutes at room temperature in the presence of 5% organic soil. Oculus Microcyn Disinfectant (OMD) is effective against E.coli in 1 minute at 20°C in the presence of 5% organic soil.

Wipe surface using a paper or cloth towel or allow to air dry. Discard towel.

FOR PRECLEANING AND DISINFECTING MEDICAL INSTRUMENTS:**FOR USE AS A PRECLEANING IMMERSION DECONTAMINANT SOLUTION:**

Fill appropriate size container with a sufficient amount of Oculus Microcyn Disinfectant (OMD) as to allow for complete submersion of instruments. Place instruments into Oculus Microcyn Disinfectant (OMD) solution, cover and allow to soak for 10 minutes at 20°C (69°F/20°C).

Remove and rinse instruments. Follow with appropriate disinfection process. When the solution becomes diluted or visibly soiled, change solution.

FOR USE AS A PRECLEANING DECONTAMINANT SPRAY:

Place instruments into suitable container. Spray Oculus Microcyn Disinfectant (OMD) onto instruments so as to thoroughly saturate all surfaces. Allow to remain wet for 30 seconds.

Remove and rinse instruments. Follow with appropriate cleaning and disinfection process. When the solution becomes diluted or visibly soiled, change solution.

FOR USE AS AN ULTRASONIC CLEANING SOLUTION:

Thoroughly pre-rinse instruments under Oculus Microcyn Disinfectant (OMD) or running water to remove visible gross debris. Fill ultrasonic unit with Oculus Microcyn Disinfectant (OMD) to a level which allows complete submersion of instrument. Immerse instruments into solution and activate ultrasonic unit for 10 minutes. Remove instruments. When the solution becomes diluted or visibly soiled, change solution.

FOR USE AS A MANUAL CLEANER:

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Thoroughly pre-rinse instruments under Oculus Microcyn Disinfectant (OMD) or running water to remove visible gross debris. Fill container with Oculus Microcyn Disinfectant (OMD) to a level which allows complete submersion of instrument. Immerse instruments into solution and scrub for 30 seconds. Allow instruments to remain submerged for 10 minutes. Remove instruments. Follow with appropriate disinfection process. When the solution becomes diluted or visibly soiled, change solution.

FOR DISINFECTING NON-CRITICAL, PRECLEANED MEDICAL INSTRUMENTS:

Instruments must be thoroughly precleaned to remove excess organic debris, rinsed and rough dried. (Clean and rinse lumens of hollow instruments before filling with solution or before immersion.) Using either a soaking tray or an ultrasonic unit, immerse instruments into Oculus Microcyn Disinfectant (OMD) solution for 10 minutes. For tuberculocidal activity, allow 5 minutes submersion at room temperature. Remove and rinse instruments. Wipe surface using a paper or cloth towel to dry prior to use. Discard towel. The solution must be discarded after each use.

Note: Critical and semi-critical devices must be followed by an appropriate terminal sterilization/high-level disinfection process.

{Note for reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, the following statements must be used}

This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean critical or semi-critical devices prior to sterilization or high-level disinfection.

FOR CLEANING HAIR CLIPPERS ELECTRIC SHEARS/RAZORS:

While clippers/shears are running, hold it in the downward position and spray Oculus Microcyn Disinfectant (OMD) directly onto the blades two or three times so as to thoroughly wet the blades. (Avoid spraying on the clippers/shears case or dripping into the clipper housing.) Allow to remain wet for 10 minutes. Wipe with a clean, soft cloth. Lubricate as per clippers/shears manufacturer's instructions.

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FOR CLEANING SALON IMPLEMENTS, SHEARS AND BARBER IMPLEMENTS:

Spray implement/shears to thoroughly wet with Oculus Microcyn Disinfectant (OMD) solution. Wipe away visible debris using a soft bristle brush or cloth. Immerse precleaned implement/shears into a container of Oculus Microcyn Disinfectant (OMD) for 10 minutes. Remove implement/shears and wipe dry. No rinsing is necessary. When the solution becomes diluted or visibly soiled, change solution.

NOTE: Upon opening this container, record the date on the container. If the product is transferred to spray bottles or other containers, record the same date on the secondary container. HPDE, PET or glass containers are recommended for secondary container storage. Oculus Microcyn Disinfectant (OMD) may be used for up to 30 days after opening. After 30 days, discard any remaining product in accordance with local, state and federal regulations.
OPEN DATE:

PHYSICAL OR CHEMICAL HAZARDS

Product contains a strong oxidizer. Always flush drain before and after use. Do not use or mix with other household chemicals such as toilet bowl cleaners, rust removers, acids, or products containing ammonia. To do so will release hazardous, irritating gases. Prolonged contact with metal may cause pitting or discoloration.

Environmental Hazard

This pesticide is toxic to fish and aquatic organisms

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{For containers one gallon or less}

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.
Oculus Microcyn Disinfectant (OMD) should be stored in its original sealed container at room temperature, away from direct sunlight and heat to avoid deterioration.
Do not reuse empty container; dispose of in trash.

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{For 2 ½ gallon containers}

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.
Oculus Microcyn Disinfectant (OMD) should be stored in its original sealed container at room temperature, away from direct sunlight and heat to avoid deterioration.

PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL

Triple rinse (or equivalent). Do not reuse empty container. Dispose of in trash or offer for recycling.